

SECTION II

In Section II, the Working Group describes the process it used to examine options for a National Materials Program. The Working Group adopted a mission, philosophy, process, and criteria for evaluating options and conducted stakeholder outreach.

Mission and Philosophy of the Working Group

The Working Group adopted a mission statement that incorporates a philosophy used in evaluating options.

Fundamental goal:

Resources should be applied to a common agenda of mutually agreed-upon goals and objectives.

Examples of duplication...

- several states have independently developed guidance for positron emission tomography
- industrial radiography rules were adopted by states, then NRC. This required many states to make conforming changes solely for compatibility purposes.

Background

The Working Group recognized that optimizing the use of state and federal resources and accommodating differing regulatory priorities would be important for state and federal agencies working within the framework of a National Materials Program.

Currently, the materials program is largely directed by NRC, which establishes regulatory priorities for byproduct, source, and special nuclear materials. Although Agreement States enjoy a participatory arrangement with NRC in some areas (e.g., rulemaking, use of working groups, etc.) under the current process, little consideration is given to Agreement State regulatory priorities that would include, in addition to AEA materials, NARM, x-ray and accelerator generated radiation, and non-ionizing radiation hazards/sources.

Both NRC and Agreement States expend resources in an effort to accommodate differing priorities. Often, regulatory agencies resolve the same issues independently, which results in a duplication of efforts and resources. **Resources should be applied to a common agenda of mutually agreed-upon goals and objectives.** With this in mind, the Working Group developed this mission statement, “The mission is to develop options for the Commission’s consideration for creating a national materials program that will implement the following philosophy:...”

Philosophy

To create a true partnership of the NRC and the States that will ensure protection of public health, safety, and the environment while:

***optimizing resources of federal, state, professional and industrial organizations
accounting for individual agency needs and abilities
promoting consensus on regulatory priorities
promoting consistent exchange of information
harmonizing regulatory approaches
recognizing state and federal needs for flexibility***

Goals of the NRC

The NRC strategic and performance goals were incorporated in criteria developed by the Working Group for evaluating potential options.

The Working Group incorporated NRC's strategic and performance goals as discussed below.

Maintain safety by establishing a regulatory oversight framework that ensures that materials licensees continue to conduct activities involving use of radioactive materials and radiation sources in a safe manner. Maintaining regulatory programs that are adequate to protect public health and safety is a priority in evaluating potential changes.

Improve the effectiveness and efficiency of regulatory programs nationwide by enhancing collaboration through exchange of information and resources, promoting consensus among regulatory agencies, and optimizing use of resources on a national level. A national program should seek to balance use of resources among the states and NRC and distribute the resource burden more equitably among Agreement State and NRC licensees. A national program should also account for individual or unique program needs and provide flexibility, which may be needed to expand or modify existing regulatory programs to ensure adequate oversight of unique or emerging technologies.

Enhance public confidence by 1) increasing consistency and predictability in regulatory approaches, while recognizing the need for flexibility among state and federal regulatory programs, and 2) improving efficiency in implementing our regulatory oversight responsibilities.

Reduce unnecessary regulatory burden by promoting a consistent regulatory approach nationwide which will offer efficiencies for licensees and greater predictability for stakeholders.

Goals of the Working Group

The Working Group identified several objectives that were used to guide its efforts in developing recommendations for a National Materials Program.

1. Optimize resources of federal, state, professional, and industrial organizations

2. Account for individual agency needs and abilities

3. Promote consensus on regulatory priorities

4. Promote consistent exchange of information

5. Harmonize regulatory approaches

6. Recognize state and federal needs for flexibility

NRC Strategic Plan, Goals and Missions of Agreement States

The primary goal of maintaining public health and safety was consistent among NRC and state programs, although other goals identified in the various strategic plans and mission statements were not consistent throughout. They were however, generally compatible.

Based on this examination, the Working Group identified six objectives that were used to guide its efforts in evaluating options and developing recommendations for a National Materials Program. These objectives incorporate the NRC's strategic goals and are reflected in the Working Group's philosophy statement on page 2.2.

Process to Develop and Evaluate Options

The Working Group developed and evaluated options for a National Materials Program.

Bottom-Up Approach...

identify what is needed in terms of outcomes or outputs rather than immediately defining relationships or processes between NRC and states

Process

The Working Group initially examined the NRC Strategic Plan and strategic goals or mission statements established by some Agreement States. Based on this information, the Working Group decided to:

1. focus on creating a functional, rather than programmatic structure by identifying outcomes (e.g., protection of public health) and outputs (e.g., rules and guidance),
2. use a bottom-up approach by looking at basic program elements common to all radiation control programs and evaluating methods to accomplish those tasks.

Functional Structure

The Working Group focused on evaluating relationships and processes that could be used by the Agreement States and NRC to achieve specific outcomes rather than initially creating new organizational structures.

Bottom-Up Approach

The Working Group wanted to identify what was needed in terms of outcomes or outputs rather than immediately defining the relationships or processes required to be formed between and used by NRC and Agreement States. The Working Group first determined what a National Materials Program should do to achieve or maintain state and federal strategic goals. This method was followed rather than using a top-down approach by immediately defining a framework for a National Materials Program.

Essential Program Elements

The Working Group began by defining essential program elements for the National Materials Program.

**program
elements
derived from...**

***Criteria for an
Adequate
Radiation
Control
Program, April
1999, and***

***NRC
Management
Directive 5.6,
Integrated
Materials
Performance
Evaluation
Program***

Essential program elements

The Working Group began by defining essential program elements for a National Materials Program. The elements were taken from *Criteria for an Adequate Radiation Control Program*, April 1999, CRCPD Publication 99-2, and from NRC Management [Directive 5.6](#), *Integrated Materials Performance Evaluation Program*. These defined the program elements to be evaluated.

For each program element, the Working Group identified the current methods used by Agreement States and NRC to accomplish the program element; then the group brainstormed alternative methods for accomplishing each program element.

The alternatives were initially assessed to ensure they supported the primary, common strategic goal of maintaining health and safety. If an alternative was not consistent with this primary goal, it was eliminated from further evaluation.

Alternatives for each program element are described in detail in Appendix C.

Evaluating Options: *Alternatives for each program element were compared to current practices, considering the six objectives of the Working Group. The alternatives were rated as being equal to, better than, or worse than the current practice. For example, each alternative for issuing materials licenses was rated with regard to optimizing resources of federal and state agencies, and professional and industrial organizations. The alternative was then rated against the existing practice for each of the remaining criteria. Based on the evaluation results, a preferred alternative, or "enhancement," was made for each program element. For some elements, the enhancement was the status quo, for some it was a new way of doing business, and for others it was a combination of alternatives.*

Enhancements to Existing Program Elements

The Working Group identified multiple enhancements that could be made to the existing methods for accomplishing these program elements.

	Enhancements
Licensing and Inspection Guidance	<ul style="list-style-type: none"> • NRC and Agreement States jointly develop an agenda and priorities for developing licensing and inspection guidance. • Use working groups to develop guidance. • Accept consensus standards (following review and revision, if needed). • Contract with other organizations to develop guidance when appropriate.
Performing Inspections	<ul style="list-style-type: none"> • Allow licensees to perform self-audits that may be accepted in lieu of inspection by NRC or an Agreement State. • Allow other entities to contract with NRC and Agreement States to perform inspections and report results to the appropriate regulatory agency. • Accept audits performed by other organizations and use these as a supplement to NRC and Agreement State inspections. • Use "Centers of Expertise" (see page 2.9) to perform inspections of specific technical areas.
Performing Licensing	<ul style="list-style-type: none"> • Use contracted entities to perform some license reviews or portions of reviews for specific technical areas. • Use Centers of Expertise to perform some license reviews or portions of reviews for specific technical areas.
Rule and Guidance Development	<ul style="list-style-type: none"> • Jointly establish agenda and priorities. • Use working groups or Centers of Expertise. • Promote development of consensus standards. • Contract with other organizations for technical support.
Training, Qualifications, and Experience Standards	<ul style="list-style-type: none"> • Use a clearinghouse of training ideas, resources, and opportunities designed for or employed by NRC and Agreement States. • Allow licensees to provide training. • Contract with licensees to train staff in specific technical areas. • Encourage a regulatory agency exchange program to develop staff in specific technical areas.

Common Themes

After reviewing the evaluations of program elements, six common themes or attributes were identified.

Consensus does not necessarily mean unanimity, but implies general agreement and provides an opportunity for all parties to bring issues, ideas, and concerns to the table for consideration.

Consensus process - Decisions concerning regulatory goals and framework should be made through a process involving both Agreement States and NRC in which general agreement is reached through a cooperative effort.

Jointly establishing regulatory priorities - Regulatory priorities should be set with common goals in mind. Agreement States and NRC should jointly, through a consensus process, determine regulatory priorities (research, rulemaking, guidance development, etc.). The schedule or plan for achieving those priorities and the best use of resources to accomplish those priorities should be coordinated.

Recognition of current successes - Agreement States and NRC have individual regulatory successes as well as successful efforts that are cooperative. Some program elements are working successfully as they now exist. Many current practices could be more successful with modifications or when enhanced with alternatives.

Recognition of individual legal and jurisdictional issues - Despite the need for consistency and cooperation, there will be situations in which Agreement States and NRC have unique legal or jurisdictional obligations that must be met. These specific obligations must not be impeded by a National Materials Program.

Shared Responsibility - Several structural options for a National Materials Program that are discussed in Section III, if fully implemented, would require more uniform resource commitment among the states and NRC.

Sharing of Resources - For a National Materials Program to be successful, all materials regulatory programs must participate. Participation means a commitment of resources, such as staff time or financial support.

Sharing of Resources

The Working Group identified several methods for sharing of resources.

Reduce duplicate efforts...

The concepts discussed under “Sharing of Resources” will assist regulatory programs to reduce duplicative efforts and save resources.

Identify and use Centers of Expertise within the existing regulatory community

Some Agreement States and NRC regions have, over time, developed considerable experience and expertise with specific uses of radioactive materials. Examples of areas of expertise include well logging, industrial radiography, positron emission tomography, and intravascular brachytherapy. Agreement States and NRC regions that have developed expertise in specific uses should be identified and used as a resource by other regulatory programs. These “Centers of Expertise” may change over time as others develop expertise.

Use alternative resources where possible

When appropriate, alternative resources should be used in conjunction with or in place of the current regulatory methods. Alternative resources can include consensus standards or enlisting the resources and cooperation of professional and industry organizations.

Establish an information infrastructure

A centralized “clearinghouse” of regulatory products should be established for use by Agreement States and NRC staffs. This could serve as a centralized source of information on the availability of rules, guidance documents, industry and professional standards, etc., and could facilitate dissemination of information.

Stakeholder Outreach - NRC's Process

The Working Group examined the current NRC stakeholder outreach process.

As part of its process, the Working Group conducted stakeholder outreach to gain comments about the Working Group's process and possible options for a National Materials Program. The Working Group began by examining the NRC stakeholder outreach process.

NRC's Stakeholder Outreach Process

Regulatory decisions must be informed decisions-- it is necessary to actively seek and consider input from those persons who would be affected.

Input from other federal and state agencies (Environmental Protection Agency, Department of Energy, and equivalent state environmental or health agencies) charged with regulating radiation issues is sought.

Other stakeholders include...

- licensees
- public
- professional organizations
- industry organizations
- other federal and state agencies with an interest in radiation issues

NRC decides when to begin rulemaking or develop policy or guidance and informs other entities that the process will begin. NRC solicits voluntary input from Agreement States and other stakeholders. Not all stakeholders choose to participate. The Commission evaluates all input appropriate in making decisions. The Commission also sets priorities and decides compatibility on the issues under development.

In addition to consulting with Agreement States and other stakeholders, the Commission uses advisory committees, such as the Advisory Committee on Nuclear Waste and the Advisory Committee on Medical Uses of Isotopes. These advisory committees are independent and autonomous from the Commission; they recommend priorities or actions that they feel the Commission should take. The Commission may accept or reject advisory committee recommendations.

The Commission contracts with various organizations for research when members believe it necessary or advisable in developing rules and guidance. This research furthers the effectiveness and efficiency of the Commission and the Agreement States in performing their regulatory functions.

The other federal and state agencies are considered stakeholders because at this time, the effort towards establishing a National Materials Program is being driven by the NRC and representatives from the state radiation regulatory agencies. It is envisioned that many of the stakeholders, i.e., other federal and state agencies and professional and industrial organizations, could become participants in the National Materials Program in the future.

Stakeholder Outreach - Communication Plan

The Working Group sought stakeholder involvement in evaluating the options for a National Materials Program.

Outreach Methods...

- Electronic Communications
- Written Communications
- Tabletop Exercise
- Public Meeting
- Focus Groups

A summary of the Working Group Outreach Activities is in Appendix B.

Stakeholder Outreach

The Working Group developed a communication plan (see Appendix B) to guide its approach in delivering its key messages and engaging the various stakeholder groups. The plan identified overall objectives, stakeholders, communication tools and opportunities, and key messages.

The Working Group provided information to various stakeholder groups on the development of the options for a National Materials Program. To obtain feedback, the Working Group used electronic and written communications, conducted counterpart and professional society meetings, tested a pilot project, met with NRC senior management, and held a public meeting.

Many stakeholders expressed satisfaction with current practices and offered suggestions that the Working Group considered in evaluating options for a National Materials Program.

Stakeholder Outreach - Communication Plan - cont'd

Electronic and written communications were important to the Working Group's outreach efforts.

Outreach publications...

Internet

Federal Register

Health Physics Society Newsletter

CRCPD Newsletter

Electronic Communications

An important component of the Working Group's outreach efforts was the establishment of an Internet site at the beginning of the process. The Working Group used the site to provide access for stakeholders to its information during the development phase of the options for a National Materials Program. The Internet site was also used to announce all Working Group meetings. List servers focusing on radiation issues for state and federal regulators were also used to solicit input during product development and to obtain information on specific issues.

Written Communications

The Working Group published notices in the *Federal Register* announcing its initial meeting in March 2000 and the public meeting in February 2001. All other meetings were posted at the Working Group's Internet site

Three articles on the National Materials Program appeared in the November 2000 *Health Physics Society Newsletter*. One of the Working Group's Co-chairs and the Chair of the Working Group Steering Committee were interviewed. The articles discussed the current regulation of radioactive material in the United States and the pros and cons of regulation by Agreement States or the NRC. These articles were available to the health physics community (regulatory and non-regulatory stakeholders) nationwide. Articles on the activities of the Working Group also appeared in the CRCPD and NRC Office of Nuclear Material Safety and Safeguards newsletters.

Stakeholder Outreach - Opportunities

The Working Group provided many opportunities for stakeholders to participate.

May 2000

Presented a poster at the annual CRCPD meeting in Tampa, Florida. The poster session introduced the mission and planned activities of the Working Group to state radiation program managers and staff.

July 2000

Provided information on the current status and activities at a meeting of standards development organizations.

July through November 2000

Provided information on the current status and activities of the Working Group to materials staff at each of the four NRC regions and at NRC Headquarters.

October 2000

Presentation and table-top exercise at the annual OAS meeting in Charleston, South Carolina.

November 2000

Provided information on the current status and activities of the Working Group at the annual New England Radiological Health Committee meeting in Mystic, Connecticut. The meeting is attended by the staff and management of the six New England states and regional federal representatives from the Food and Drug Administration, Environmental Protection Agency, Federal Emergency Management Agency, NRC, and Canada.

Presented information to the regulated community in Texas at a meeting of the South Texas Chapter of the Health Physics Society. A focus group session was held after the presentation to obtain feedback on specific questions.

January 2001

Presented information to the regulated community in Georgia at a meeting of the Atlanta Chapter of the Health Physics Society.

February 2001

The Working Group held a public meeting in Arlington, Texas, to discuss the various options for a National Materials Program. The Working Group obtained feedback from a focus group of individuals who represented a wide spectrum of regulatory and non-regulatory stakeholders. After a presentation on the options described in Section III of this paper, the Working Group facilitated a discussion using a set of questions to obtain feedback and comments.

March 2001

Presented information to the regulated community at a meeting of the New Jersey Chapter of the Health Physics Society.

April 2001

Presented update on the status of the Working Group activities at the annual CRCPD meeting in Anchorage, Alaska.

Stakeholder Outreach - Tabletop Exercise

A tabletop exercise provided an opportunity to apply some of the National Materials Program concepts and obtain feedback.

Consensus Building with Tabletop Exercise

Participants brought a list of their three top regulatory priorities over the next 7 to 28 months.

The priorities were consolidated into a single list.

The participants reached consensus on the priorities.

A group of states decided to pool their resources to work on one of the priorities.

On October 2 and 3, 2000, the Working Group held tabletop exercises for consensus building on determining the agenda for regulatory priorities at the annual OAS meeting. In addition, the Working Group gave a presentation on the current status and activities of the Working Group.

Prior to the OAS meeting, the Working Group requested that each Agreement State and NRC bring a list of their three top priorities over the next 7 to 28 months in the areas of regulations and guidance development. The priorities for each state and NRC were collected and consolidated into a single list. Copies of the consolidated list were given to each agency participant. Working Group members facilitated an exercise with the participants to reach consensus on the priorities provided by each agency.

A priority item identified by a number of states was the need for licensing guidance for positron emission tomography (PET). The Working Group considered the tabletop exercise a success because, as a result of this exercise, a group of states led by the State of Washington decided to pool their resources and develop the necessary PET licensing guide.

The interaction, discussion, and action taken on the PET licensing guidance was an important event for the Working Group in terms of stakeholder outreach because it was an opportunity to have stakeholders apply some of the National Materials Program concepts and obtain their feedback. Continuing feedback to the Working Group has been positive and development of PET guidance is ongoing.

Stakeholder Outreach - Public Meeting

Options for a National Materials Program were discussed during a public meeting.

Feedback from public meeting...

- **federal agencies should stop creating conflicting standards**
- **NRC should regulate discrete NARM**
- **Some entity should be "in charge" of a National Materials Program**
- **NRC should be willing to modify the AEA**
- **a National Materials Program should improve consistency, but allow flexibility**

A public meeting was held February 21 and 22, 2001, in Arlington, Texas, to discuss the various options for a National Materials Program and obtain feedback from a focus group of individuals representing a wide spectrum of regulatory and non-regulatory stakeholders. The stakeholders included representative from NRC, Agreement States, non-Agreement States, licensees, professional societies, environmental groups, other non-governmental organizations, and organizations representing specific categories of licensees.

For each potential National Materials Program option, the focus group participants discussed how it impacted the following:

- access to decision makers
- budget/resource implications
- legal authority
- efficiency
- uniformity/consistency
- flexibility
- comprehensiveness
- stability
- role of NRC, Agreement States, and other organizations
- rationale for change
- accountability
- practicality

The focus group participants recognized that there are options within each option for a National Materials Program and, in some situations, options can be combined. Input from the participants helped the Working Group define the options for a National Materials Program that are outlined in Section III.